UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,466	01/26/2004	Sachiko Machida	690115.401C1	8356

500 7590 06/12/2006

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,466	MACHIDA ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,15-17 and 40-43* is/are pending in the application.

4a) Of the above claim(s) *40-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants amendment filed 27 March 2006 has been entered. Claims 2-14 and 18-39 have been canceled. Claims 1, 15-17 and 40-43 are currently pending in this application.

Election/Restrictions

2. Newly submitted claims 40-43 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions of a) claims 1 and 15-17 and b) claims 40-43 are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions are mutually exclusive, are not obvious variants and have materially different design because the product of group a requires product limitations that are not required of the product of group b. The product of group a requires the receptor protein having the ability to specifically bind a ligand of the receptor protein, which is not required of the product of group b. The product of group b requires a polypeptide comprising a biotinylation sequence motif, which is not required of the product of group a.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 40-43 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Withdrawn Rejections

3. Previous rejections of claims 2-14, 32, 34 and 36-38 have been withdrawn in light of applicant's amendment and cancellation of claims.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is drawn to a receptor chip that is adapted for detection using a particular method, but it is unclear how the adaptation affects the product of the structure of claim 1. It is unclear whether the adaptation for a specific detection method requires any further product limitations. It is further unclear what structural limitations the receptor chip requires in order to provide the adaptation for a specific detection method. The claim must recite the structural limitations required for adaptation rather than mere recitation of adaptation for a specific detection method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-15, 32 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Holtzman et al. (US 2002/0055139).

Holtzman et al. teach a receptor chip (96 well plates, par. 698) on which a recombinantly expressed receptor protein (TANGO 402 proteins can be used as receptors for Ox-LDL, par. 92) is immobilized via factor capable of specifically binding to biotin (par. 698). Although Holtzman et al. do not specifically teach the biotinylation of the receptor protein being carried out within a bacterial host; such a limitation is drawn to a product by

process, which is not given patentable weight. Furthermore, the receptor protein of Holtzman et al. is capable of being biotinylated within a bacterial host.

Regarding claim 15, Holtzman et al. teach the receptor protein able to bind to Ox-LDL, which therefore makes the receptor protein part of a LDL receptor related protein family (par. 92).

Claim Rejections - 35 USC § 103

1. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holtzman et al. (US 2002/0055139), as applied to claims 1 and 32, in view of Moriwaki et al. (Arterioscler Thromb Vasc Biol 1998 18: 1541-1547).

Holtzman et al. teach a receptor chip comprising immobilized receptor protein of the LDL receptor related protein family, but do not teach the receptor protein being LOX-1.

Moriwaki et al. teach a receptor protein of LOX-1 (pg. 1545, left column, section: *LOX-1 binds to protein moiety of Ox-LDL*), in order to define ligand specificities of LOX-1.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to immobilize on the receptor chip of Holtzman et al., a receptor protein of LOX-1 as taught by Moriwaki et al., in order to provide a more efficient testing surface by accommodating automation of the assay and facilitating separation of complexed and uncomplexed forms of LOX-1.

2. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holtzman et al. (US 2002/0055139), as applied to claim 1, in view of Duffy et al. (US 2003/0032076).

Holtzman et al., teach a receptor chip comprising an immobilized receptor protein, but fail to teach the receptor chip adapted for detection by mass spectrometry.

Duffy et al. teach adapting a surface (par. 186) for use with ELISA or SPR (par. 186), in order to detect molecules.

It is well known in the art, as evidenced by Duffy et al., that ELISA detection is functionally equivalent to SPR detection, and the same adapted substrate can be used for both ELISA and SPR detection. It would have been obvious to substitute the SPR detection, as taught by Duffy et al., for the ELISA detection taught by Holtzman et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent detection technique since the expected measurement effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill based on the economics and availability of detection equipment.

Response to Arguments

6. Previous rejections of claims 2-14, 32, 34 and 36-38 under 35 USC 112, second paragraph have been withdrawn.

7. Applicant's arguments filed 27 March 2006 have been fully considered by they are not persuasive.

8. At page 5, regarding the rejection of claim 17 under 35 USC 112, second paragraph, applicant argues that a skilled artisan would readily appreciate that receptor chips adapted for various specific detection methods possess distinct characteristics as compared to the receptor chip of claim 1. However, in response to applicant's argument, structural limitations required for the adaptation of a receptor chip for various detection methods must be recited in the claim for the claim to be rendered definite.

9. At pages 5-10, applicant argues that recombinantly expressed protein taught by Holtzman et al. is different than the recombinantly expressed protein recited in the instant claims. Applicant argues that the biotinylated proteins produced *in* vivo and *in vitro* are different because they are made by different processes. Applicant further argues that the recombinantly expressed protein of the claimed protein is produced by a method of

biotinylation *in vivo* (in a bacterial host) is different from the recombinantly expressed protein taught by Holtzman et al., because the protein of Holtzman is produced by a method of biotinylation *in vitro*. Applicant argues that *in vitro* biotinylation methods, as taught by Holtzman et al., produce a recombinantly expressed protein wherein the protein contains moieties attached to various lysine residues throughout the protein, while the *in vivo* biotinylation methods produce a protein containing a single biotin moiety attached to a specific lysine residue within the biotin ligase target sequence.

10. Firstly, applicant's arguments are not persuasive because the arguments are drawn to a product-by-process limitation, which is not given patentable weight. Secondly, applicant's arguments are not persuasive even if the final product of the product-by-process limitation were given patentable weight because the end product of an *in vitro* biotinylation method reads on the end product of an *in vivo* biotinylation method. As applicant explains at page 6, third paragraph to page 7, first paragraph, a protein biotinylated *in vivo* has a single biotin moiety attached to a specific lysine residue. In response to applicant's arguments, as explained by applicant at page 6, second paragraph, the biotinylated protein resulting from *in vitro* biotinylation also comprises biotin moieties at various lysine residues. Since claim 1 contains open claim language "comprising", the protein resulting from a biotinylation *in vivo* does not exclude more than one biotin moieties attached to various lysine residues. Therefore the protein biotinylated *in vitro* comprises at least a single biotin moiety attached to a specific reside (whatever lysine residue to which the biotin moiety is attached is considered a specific residue). Therefore, the protein produced by *in vitro* biotinylation reads on the protein produced by *in vivo* biotinylation, and the protein of Holtzman et al. reads on the protein recited in the instant claims. Thirdly, applicant's arguments are not persuasive because Holtzman et al. teach the structural limitations recited by instant claim 1, and the instant claims do not specifically recite the specific

structural limitations that are different between a protein biotinylated *in vivo* and a protein biotinylated *in vitro*.

Conclusion

No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Yu
Patent Examiner
Art Unit 1641

LONG V. LE 06/07/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600